

52. The method of claim 51, wherein said donor cell is a non-human primate oocyte or embryonic cell and the recipient is a human somatic cell.

53. The method of Claim 38, wherein de-differentiation of the recipient cell results in the production of an embryonic stem cell.

REMARKS

This Reply is responsive to the Office Action dated August 13, 2002. Claims 17-25 and 33-35 are canceled, claims 1, 5-11, and 26 are amended, and new claims 36-53 are added. Entry of the foregoing and reconsideration on the merits is respectfully requested.

Independent claims 1 and 26 are amended to include the limitations that the recipient cell is a differentiated cell, and the introduction of cytoplasm does not result in production of an embryo. Claims 5-11, 26, and 32 are amended to remove ambiguities and correct informalities. New claims 38-53 are directed to method that includes the limitation that the de-differentiated cell is cultured under conditions in which it differentiates. No new matter is added by the amendment

Support in the Specification for the Amendments:

Support for amending claims 1 and 26 to recite a method in which the recipient cell is a differentiated cell is found, for example, on page 12, lines 24-31. Support for the method of claims 1 and 26 comprising "de-differentiating" the recipient cell is found, for example, on page 11, lines 12-13. Support for the method wherein introduction of cytoplasm into the recipient cell does not result in production of an

embryo is found, for example, on page 4, lines 18-20. Support for amending claim 6 and 7 to recite a method in which the recipient cell is a mammal selected from the listed species is found, for example, on page 12, lines 18-23. Support for amending claim 8 to recite a method in which the recipient cell is selected from the listed cell types, including spleen, kidney, and thymus, is found, for example, on page 12, lines 24-31. Support for the method of new claims 38-53 wherein the de-differentiated cell is cultured under conditions in which it differentiates is found in the specification, for example, on page 14, lines 18-20; and page 16, lines 6-10.

Rejections of claims under 35 U.S.C. §112, second paragraph:

Claims 5-11 and 26-32 were rejected under 35 U.S.C. §112, second paragraph as being indefinite. Claim 5-8 are amended to clearly identify the recited cell; and claim 9 is amended by replacing "and/or" with "or". The phrases "effective amount" and "biologically pure" are removed from claims 26 and 32, respectively. Withdrawal of the rejection of claims 5-11 and 26-32 under 35 U.S.C. § 112, 2nd paragraph, is respectfully requested.

Rejections of claims under 35 U.S.C. §102(b)

Claims 1, 2, 5-8, 14-16, 26, 28, 29, and 32 were rejected under 35 U.S.C. §102(b) as being anticipated by Willadsen (1987), Wilmut et al. (1997), or Robl et al. (Appl. No. 20010012513). The Applicants respectfully traverse these rejections. All three of the cited references describes fusing a nuclear donor cell with an enucleated oocyte so as to produce an embryo. None of the references disclose introducing cytoplasm of an oocyte or embryonic cell into a differentiated cell in culture in order to effect re-programming or alteration of life-span; e.g., to produce de-differentiated cells

that can be induced to differentiate into different, useful cell types, as described in the present application. Independent claims 1 and 26 are amended to specify methods wherein the introduction of cytoplasm does not result in production of an embryo. This feature of the invention is taught in the specification (page 4, lines 18-20), and clearly distinguishes the claimed invention from the methods of the prior art. Accordingly, the Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 102(b) be withdrawn.

Rejections of the claims under 35 U.S.C. §103(a)

Claims 3, 4, 9-13, 27, 30, and 31 were rejected under 35 U.S.C. §103(a) as being obvious in view of Willadsen (1987), Wilmut et al. (1997), or Robl et al, each in combination with Thomson et al. (1998) and Greider et al. (WO 97/35967).

As noted above, the claims to recite the limitation that the introduction of cytoplasm into the recipient cell does not result in production of an embryo. None of the three primary references cited in the rejections under 35 U.S.C. §103(a) discloses or suggests introducing cytoplasm of an oocyte or embryonic cell into a differentiated cell in culture in order to effect reprogramming or alteration of life-span without production of an embryo. The cited secondary references do not remedy this deficiency. Thomson and Greider are cited for their teachings with respect to telomerase. There is nothing in the cited references that would suggest making or using the claimed invention to a person of ordinary skill in the art. Accordingly, the Applicants respectfully request that the rejections of the claims under 35 U.S.C. § 103(a) be withdrawn.

The above amendment and remarks are fully responsive to the Office Action. If there are any issues remaining that need to be resolved, the Examiner is respectfully requested to contact the undersigned so that allowance of this application can be expedited.

Respectfully submitted,

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APPENDIX

Claims 1, 5-11, 26, and 32, are amended as shown below:

1. (Amended) A method for reprogramming and/or altering the life-span of a differentiated cell [a desired cell ("recipient cell")] comprising introducing into [such] a differentiated recipient cell cytoplasm from another less differentiated or undifferentiated donor cell to effect de-differentiation of the recipient cell;

wherein said introduction of cytoplasm does not result in production of an embryo.

5. (Amended) The method of Claim 1, wherein said recipient and donor cells [is a] are mammalian cells.

6. (Amended) The method of Claim 5, wherein said [mammalian] recipient cell is derived from a mammal selected from the group consisting of non-human primate, human, rat, guinea pig, mouse, rabbit, dog, cat, hamster, goat, cattle, sheep, horse, bison and buffalo.

7. (Amended) The method of Claim 5, wherein said [mammalian] recipient cell is a human somatic cell.

8. (Amended) The method of Claim [7] 5, wherein said [mammalian] recipient cell is selected from the group consisting of cardiac, lung, skin, liver, spleen,



kidney, thymus, stomach, intestine, neural, muscle, bone, cartilage, immune, pancreatic, spleen, esophageal, and corneal cells.

9. (Amended) The method of Claim 1, wherein said recipient cell[s are] is genetically modified prior, concurrent [and/]or subsequent to the introduction of said cytoplasm.

10. (Amended) The method of Claim 9, wherein said genetically modified cell[s] comprises several genetic modifications.

11. (Amended) The method of Claim 9, wherein said genetically modified recipient cell[s] comprises a recombinant DNA that encodes for a desired polypeptide.

26. (Amended) A method for producing a culture comprising embryonic stem cells comprising introducing cytoplasm from a donor oocyte or embryonic cell into a differentiated mammalian cell in tissue culture [containing an effective amount of cytoplasm from a donor oocyte or embryonic cell of the same or different species as the mammalian cell] to effect de-differentiation of the recipient cell into an embryonic stem cell; wherein said introduction of cytoplasm does not result in production of an embryo.

32. (Amended) A [biologically pure] culture comprising embryonic stem cells produced by the method of Claim 26.